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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,491	06/15/2007	Simon Davis	IS1.103	4177
23557	7590	03/18/2010	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	
			NOTIFICATION DATE	DELIVERY MODE
			03/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[euspto@slspatents.com](mailto:euspto@slspatents.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/585,491	DAVIS, SIMON	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 November 2009 and 08 February 2010.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 62 and 66-73 is/are pending in the application.  
 4a) Of the above claim(s) 67-72 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 62,66 and 73 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 June 2007 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/29/07;11/11/09</u> .                                       | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

1. Applicant's amendments and remarks filed on 11/11/2009 and 02/08/2010 are acknowledged.

Claims 62 and 66 – 73 are pending.

2. Applicant's election with traverse of the sub-species of peptide PALLVV (SEQ ID NO:44) of the previously elected Species of PD-1 in the reply filed on 11/11/2009 is acknowledged.

The traversal is on the grounds that the cited reference of Hunig et al. allegedly does not support a finding that the claimed invention fails to define a contribution over the prior art.

This is not found persuasive fro the reasons set forth in detail in the art rejection below.

The requirement is still deemed proper and is therefore made FINAL.

Examination has been extended to include the species of SEQ ID NO:61.

Claims 67 – 72 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

**Claims 62, 66 and 73 are presently under consideration.**

3. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claims 62, 66 and 73 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 62, 66 and 73 are indefinite in the recitation of “superagonistic signaling” as the term applies to cell surface receptors other than costimulatory receptors of the immune system. Neither the claims nor the specification define the term, and therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

B. Claims 62, 66 and 73 are indefinite in the recitation of “membrane proximal region,” because neither the reference point nor the degree of proximity have been defined.

C. Claims 62, 66 and 73 are indefinite in the recitation of an antibody which does not bind “only” the human PD-1 equivalent of the C”-D loop of human CD28, because it is unclear what the word “only” is intended to exclude: non-human PD-1 equivalents, human non-PD-1 equivalents, equivalents of regions other than the C”-D loop, or some other entity defined by a different combination of the recited terms.

D. Claims 62, 66 and 73 are indefinite in the recitation of human PD-1 “equivalent” of the C”-D loop of human CD28, because the nature or degree of the requisite equivalence have not been defined. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Art Unit: 1644

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

5. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

6. Claims 62, 66 and 73 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the claimed antibody, because Applicant is not in possession of the generically recited “cell surface receptor.”

One of skill in the art is aware that the genus of cell surface receptors encompasses molecules which are unrelated in structure and function. In the absence of a disclosure in the instant specification of sufficiently detailed, relevant identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, the skilled artisan cannot envision all the contemplated cell surface receptors encompassed by the instant claims.

Art Unit: 1644

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

7. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) *the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

(b) *the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

(e) *the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

8. Claims 62, 66 and 73 are rejected under **35 U.S.C. 102(a)** and **35 U.S.C. 102(e)** as being anticipated by Hunig et al. (US Pat. Pub. No. 2003/0166860; of record; see entire document).

Hunig et al. teach an antibody which binds to PD-1 epitope LAAFPEDRSQPGQDCR (see entire document, in particular e.g. the boxed area in Figure 7a). This epitope is identical in sequence to the instantly recited SEQ ID NO:61, as can be assessed by visual inspection. Since the antibody taught by Hunig et al. has the same binding specificity as the instantly recited antibody, it inherently has the same functional properties, including the ability to induce superagonistic signaling.

Claim 66 is included in the rejection because the instant antibodies are claimed as binding an epitope “comprising” the recited amino acid sequence, and as such are not limited to binding the recited sequence.

Therefore, the teachings of the reference anticipate the instant claimed invention.

9. Claims 62, 66 and 73 are rejected under **35 U.S.C. 102(b)** as being anticipated by Wood et al. (US Pat. Pub. No. 2002/0160000; see entire document).

Wood et al. teach antibodies to PD-1 (e.g. claim 3).

It is noted that the instant antibodies are claimed as binding an epitope “comprising” the recited amino acid sequence, and as such are not limited to binding the recited sequence. Therefore, based on the present record, the claimed and referenced antibodies appear to have equivalent binding specificities. The Office is not in a position to test the antibody described in the prior art for the functional properties recited in the instant claims. The burden is on the applicant to establish a patentable distinction between the claimed and referenced antibodies. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Since the antibody taught by Wood et al. is presumed to have the same binding specificity as the instantly recited antibody, it inherently has the same functional properties, including the ability to induce superagonistic signaling.

Therefore, the teachings of the reference are deemed to anticipate the instant claimed invention.

**10. Conclusion: no claim is allowed.**

Art Unit: 1644

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/

ILIA OUSPENSKI, Ph.D.

Primary Examiner

Art Unit 1644

March 12, 2010